Notices

Federal Register
Vol. 60, No. 80
Wednesday, April 26, 1995

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Partially Closed Meeting

Committee: Malaria Vaccine Program Advisory Committee.

Date and Location: TvT Conference Room, 1601 North Kent Street, Suite 1104, Arlington, VA 22209.

1. April 27, 9 am–1 pm, (open session)
2. April 27, 1 pm–2:00 pm, (closed session)
3. April 27, 2 pm–5:00 pm, (open session)

Agenda: The committee will (1) review progress towards malaria vaccine development by USAID-funded and other invited investigators and (2) review procurement actions, both current and planned. Closed Meeting: Portions of the meeting are closed under exemption 9(B) of 5 U.S.C. 552(b) to discuss proposals, scopes of work, cost estimates, and other sensitive procurement information. Disclosures of such information would be likely to significantly frustrate implementation of current and futures procurement by USAID.

FOR FURTHER INFORMATION CONTACT: Steve Landry, Ph.D., Malaria Vaccine Development Program, USAID Office of Health and Nutrition, (SA–18 Room 1238), Washington, DC 20523–1817, (703) 875–4508. John Tomaro, Chief, Environmental Health Division, Office of Health and Nutrition, Center for Population, Health and Nutrition, Bureau for Global Programs, Field Support and Research.

Dated: April 21, 1995.

Mike Kitay,

Office of the General Counsel.

Charge to the Scientific Consultants Group

April 27, 1995.

The Scientific Consultants Group (SCG) is charged with providing USAID with advice regarding its efforts to develop vaccines against malaria. During this meeting, the SCG is requested to make comments and recommendations in the following areas:

(1) The role of the SCG
(2) The MVDP progress on:
- MAP Initiative
- MSP–1 Initiatives
- MVDP Primate Program
- Field Studies in Kenya

(3) The appropriateness of MVDP plans for new activities:
- SERA Initiative
- AMA–1 Initiative

(4) The MVDP processes for selecting and developing new antigens
(5) The coordination among USAID/TDR/CEC
(6) The projected future scope and direction of the MVDP

USAID-Malaria Vaccine Development Program, Meeting of the Scientific Consultants Group

April 27, 1995.

9:00 a.m. to 5 p.m.

- Welcome—Representative of the Office of Health and Nutrition.
- Announcements/Introductions—Dr. Steve Landry.
- Review of Agenda—Dr. Steve Landry/Dr. Robin Powell.
- Approval of Winter '94 Minutes—Dr. Robin Powell/SCG Members.
- Review of the Role of the SCG—Dr. Steve Landry/Dr. Robin Powell.
- Discussion and Comment—SCG Members.
- Charge to the SCG—John Tomaro/Dr. Robin Powell.

Coffee Break

- MVDP Update.

Current Initiatives-Overview—Dr. Steve Landry
MAP Initiative—Dr. Carter Diggs
MSP–1 Initiatives—Dr. Carter Diggs
MVDP Primate Program—Dr. Steve Landry
Field Studies in Kenya—Dr. Steve Landry
Discussion and Comment—SCG Members

New Initiatives
SERA Initiative—Dr. Carter Diggs
AMA-1 Initiative—Dr. Carter Diggs
Discussion and Comment—SCG Members

Lunch

- MVDP process for selecting developing new antigens (closed session—Drs. Landry and Diggs.
- Discussion and Comment (closed session)—SCG Members.
- MVDP/TDR/CEC Coordination—Dr. Steve Landry.
- Discussion and Comment—SCG Members.
- Future directions/priorities for the MVDP—Drs. Landry and Diggs/SCG Members.
- Discussion and Comment—SCG Members.
- Deliberations, Conclusions and Recommendations—SCG Members.
- Debriefing—SCG/David Oot.
- Plans for the next meeting.

[FR Doc. 95–10269 Filed 4–25–95; 8:45 am]
BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 95–031–1]

Availability of Environmental Assessment and Finding of No Significant Impact

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment and a finding of no significant impact for the issuance of a conditional veterinary biological product license. A risk analysis, which forms the basis for the environmental assessment, has led us to conclude that issuance of this conditional license will not have a significant impact on the quality of the human environment. Based on our finding of no significant impact, we have determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact may be obtained by writing to the person listed under **FOR FURTHER INFORMATION CONTACT.** Please refer to the docket number of this notice when requesting copies. Copies of the environmental assessment and finding of no significant impact (as well as the risk analysis with confidential business information removed) are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Jeanette Greenberg, Veterinary Biologics, BBEP, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–

1237; telephone (301) 734–8400; fax (301) 734–8910.

SUPPLEMENTARY INFORMATION: A veterinary biological product regulated under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR part 102 regarding the licensing of biological products provide that a conditional veterinary biological product license may be issued to meet an emergency situation, limited market, local situation, or other special circumstance. The special circumstance addressed here is the current raccoon rabies epizootic in the United States. The product being issued a conditional license is intended for vaccinating raccoons against rabies. No other licensed product is currently available for this purpose. The vaccination of raccoons is proposed to limit the further spread of the raccoon rabies epizootic, and to prevent the spread of rabies to domestic animals and to humans. Conditionally licensed products are required to be pure and safe, and have a reasonable expectation of efficacy.

In determining whether to issue a conditional license for the veterinary biological product referenced in this notice, the Animal and Plant Health Inspection Service (APHIS) conducted a risk analysis to assess the product's potential effects on the safety of animals, public health, and the environment. Based on that risk analysis, APHIS has prepared an environmental assessment. APHIS has concluded that issuance of a conditional veterinary biological product license for the veterinary biological product referenced in this notice will not significantly affect the quality of the human environment. Based on the finding of no significant impact, we have determined that there is no need to prepare an environmental impact statement.

An environmental assessment and a finding of no significant impact have been prepared for the issuance of a conditional veterinary biological product license for the following veterinary biological product: Rabies Vaccine, Live Vaccinia Vector; Code 1901.R0; to be issued to Rhone Merieux, Inc., Establishment License No. 298. This recombinant rabies vaccine is intended for vaccinating raccoons against rabies, and is not intended for use in pets. The conditional license restricts the use of this product to State or Federal Government agencies administering wildlife rabies control programs. The availability of the recombinant rabies vaccine for use in rabies control programs may be useful in limiting the spread of the current rabies epizootic in the United States.

A conditional license has been issued on the basis that the product has been demonstrated to be pure and safe, and to have a reasonable expectation of efficacy. The product has not met the efficacy requirements of title 9, Code of Federal Regulations, § 113.312 for rabies vaccines; however, a reasonable expectation of efficacy has been demonstrated in the studies that have been conducted to date. The efficacy of this recombinant rabies vaccine will be further evaluated during the conditional license period. The State and Federal Government agencies using the rabies vaccine will be provided with detailed instructions for safely using the recombinant vaccine. These instructions include continued use of the following mitigative procedures that have been implemented for the field tests previously conducted with this product:

1. Public education efforts, including education efforts directed at school-aged children, should be conducted prior to distributing the baits containing the recombinant rabies vaccine. Warning labels should be attached to the baits to minimize the possibility of accidental exposure of members of the local populations in the areas where the vaccine-laden baits are distributed. The warning labels should clearly identify the recombinant vaccine and list the phone number for the local public health authorities. The public education efforts should be conducted prior to distributing the baits and should include newspaper articles, local television reports, and the distribution of brochures and posters. Public information meetings may also be used. In addition, when the baits are distributed, signs should be posted at the periphery and at strategic points within the distribution area notifying visitors of the rabies control efforts and warning them not to disturb the vaccine-laden baits.

2. The local public health authorities in the areas where the recombinant rabies vaccine is used should be notified prior to the distribution of the baits. The public health authorities should be instructed to inform the authorizing State or Federal Government agency of any reported human contacts with the vaccine-laden baits. Individuals who may have been exposed to the vaccine should be examined for any adverse reactions or clinical signs of orthopoxvirus infection, and have blood samples drawn and analyzed for the presence of antibodies of rabies and/or vaccinia.

3. The personnel conducting the rabies control programs should be trained in the appropriate precautions and techniques for assembling, handling, and distributing the vaccine-laden baits. These personnel should be encouraged to be vaccinated against vaccinia, as recommended by the U.S. Public Health Service [Morbidity and Mortality Weekly Report; Recommendations and Reports; Vaccinia (Smallpox) Vaccine, Recommendations of the Immunization Practices Advisory Committee (ACIP), Vol. 40, pp. 1–10 (1991)], and also be vaccinated against rabies. All personnel should be non-pregnant adults at least 18 years of age, who are free of any known immunosuppressive conditions. Regular blood samples should be collected from the personnel and monitored for the presence of rabies and vaccinia antibodies.

4. The filling of the liquid vaccine into ampules for assembly into the baits should be conducted according to Biosafety Level-2 (BL–2) criteria [CDC–NIH Manual: Biosafety in Microbiological and Biomedical Laboratories, Third Edition (1993) pp. 18–24].

5. Any adverse reactions observed in the areas where the recombinant rabies vaccine is used should be reported to the licensed manufacturer, who will forward this information to Veterinary Biologics, APHIDS.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS NEPA Implementing Procedures (60 FR 6000–6005, February 1, 1995).

Done in Washington, DC, this 20th day of April 1995.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–10241 Filed 4–25–95; 8:45 am]

BILLING CODE 3410–34–M